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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,208	10/29/2001	Hiroyuki Odaka	2530 US1P	4444

23115 7590 06/18/2003

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EXAMINER
COOK, REBECCA

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,208	ODAKA ET AL.	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11 and 22-27* is/are pending in the application.

4a) Of the above claim(s) *11 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 22, 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicants have elected the insulin sensitizer pioglitazone and the anorectic sibutramine. Claims 1-7, 11, 22-27 are being examined.

The replacement abstract has been received.

Claims 1-7, 11, 22, 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support is seen on page 32 for the recited method for lowering the concentration of glycosylated hemoglobin.

Applicants' argument that Example 1 discloses an exemplary combination treatment is not persuasive. The example provides support lowering the concentration of glycosylated hemoglobin for only the insulin sensitizer pioglitazone HCl and the anorectic mazindol and only at the dosage recited in example 1. Furthermore, the specification discloses on page 32 that glycosylated hemoglobin is merely an index of blood sugar control.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for leptin, glucagons-like peptide 1 and corticotropin releasing hormone, does not reasonably provide enablement for the analogues of these compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. It would take undue experimentation to determine which compounds are intended to be included as analogues and whether the intent is to

include structural as well as functional analogues and the specification provides no guidance as to which compounds are intended to be included as analogues.

Claims 3, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3 the recitation "or their salts" renders the claim confusing as to whether all salts are claimed. Amending the claim to recite "or a salt thereof" will overcome this rejection.

There is no antecedent basis in claim 2 for the recitation in claim 11 "formula (I)."

In view of applicants' argument the rejections on the ground of Judicially Created Doctrine as being drawn to a compound with no common core and under 35 USC 112, second paragraph are withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7; 11, 22, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 749 751 (Ikeda) (page 2, lines 35-58, page 7, lines 45-58, among others) in view of Kheir El-Din et al (abstract, page 363) and WPIDS 1990-361604(Sundrehagen et al) (abstract).

'751, Ikeda, discloses that insulin sensitizers, including the one of claims 1-4, 11 are used to treat diabetes. Ikeda et al do not disclose the anorectic recited in the claims or a method for lowering the concentration of glycosylated hemoglobin. Dependent claims further recite administering the compounds together or separately.

However, Kheir El-Din et al disclose that the anorectic mazindole, recited in claims 1, 5-7 and 22, is used in combination with a hypoglycemic compound.

Furthermore, '604, Sundrehagen, discloses that glycosylated hemoglobin is a marker for glycemic control and used to monitor control of blood glucose. It would be obvious to one of ordinary skill in the art that using the insulin sensitizer of Ikeda in combination with the anorectic of Kheir El-Din would lower glycosylated hemoglobin, since the art discloses that they each improve glycemic control in diabetics. This would be seen when glycemic control in a diabetic is monitored by measuring glycosylated hemoglobin. Additionally, there is nothing unobvious about administering compounds together or separately and once a method of use of compounds is known it is within the skill of the artisan to determine the optimum method of use.

Claims 1-5, 11, 22, 24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 749 751 (Ikeda) (page 2, lines 35-58, page 7, lines 45-58, among others) in view of DRUGU AN 1999-29667 (Heath) (abstract) in view of WPIDS 1990-361604 (Sundrehagen) (abstract).

'751, Ikeda, discloses that insulin sensitizers, including the one of claims 1-4, 11 and 25 are used to treat diabetes. Ikeda does not disclose the anorectic recited in the

claims or a method for lowering the concentration of glycosylated hemoglobin. Dependent claims further recite administering the compounds together or separately.

However, '667, Heath, discloses that the anorectic sibutramine, recited in claims 5, 22, 24-25 improves glycemic control and lowers glycosylated hemoglobin.

Furthermore, Sundrehagen discloses that glycosylated hemoglobin is a marker for glycemic control and used to monitor control of blood glucose. It would be obvious to one of ordinary skill in the art that using the insulin sensitizer of Ikeda in combination with the anorectic of Heath would lower glycosylated hemoglobin, since the art discloses that they each improve glycemic control in diabetics and Heath further discloses that sibutramine lowers glycosylated hemoglobin. Additionally, there is nothing unobvious about administering compounds together or separately and once a method of use of compounds is known it is within the skill of the artisan to determine the optimum method of use.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 749 751 (Ikeda) (page 2, lines 35-58, page 7, lines 45-58, among others) and DRUGU AN 1999-29667 (Heath) (abstract), WPIDS 1990-361604(Sundrehagen et al) (abstract) as applied to claim 1 above, and further in view of WPIDS 1997-535361 (Holst) abstract).

Claim 23 differs over the references in reciting specific anorectic compounds. However, '361, Holst, discloses that glucagons-like peptide 1 can be used to treat obesity and type II diabetes.

It would be obvious to one of ordinary skill in the art that using the insulin sensitizer of Ikeda in combination with the anorectic of Holst would lower glycosylated hemoglobin, since the art discloses they each improve glycemic control in diabetics and Sundrehagen discloses that glycosylated hemoglobin is a marker for glycemic control and used to monitor control of blood glucose.

The Declaration of March 7, 2003 by Dr. Odaka submitted under 37 CFR 1.132 has been carefully considered and is persuasive for a method for lowering the concentration of glycosylated hemoglobin in a mammal using the insulin sensitizer pioglitzone in combination with the anorectic sibutramine of claim 25 only.

Applicants' argument that the results of the Declaration are indicative of non-obviousness of the aspects of the invention set forth in independent claim 1 is not persuasive in the absence of a showing commensurate in scope with the claim.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 11, 22-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-25 of U.S.

Patent No. 6,329,404 in view of Sundrehagen et al for the reasons given in Paper No. 7. Although the conflicting claims are not identical, they are not patentably distinct from each other because Sundrehagen discloses that glycosylated hemoglobin is a marker for glycemic control and is used to monitor control of blood glucose. It would be obvious to one of ordinary skill in the art that using an insulin sensitizer in combination with an anorectic would lower glycosylated hemoglobin, sine the art discloses that they each improve glycemic control in diabetics and this would be seen when glycemic control in a diabetic is monitored by measuring glycosylated hemoglobin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Rebecca Cook

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200 1614

June 16, 2003